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EXAMINER

BAHTA, KIDEST

ART UNIT	PAPER NUMBER
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2123

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/788,770

Applicant(s)

BISCUP, ROBERT S.

Examiner

KIDEST BAHTA

Art Unit

2123

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/8/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-62 and 64-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-62 and 64-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43-47, 53-60, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crook (US Patent 5,365,996) in view of Fuss et al. (US 6,562,072).

Regarding claims 43, Crook discloses that a method for producing a custom prosthetic implant for insertion into a obtaining information about the site of implant for the prosthetic implant (Abstract); manually and/or electronically entering said obtained information about said site for processing by at least one data processor (column 3, lines 32-41); processing said manually and/or electronically entered information by said at least one data processor to generate data for a multi-dimensional prosthetic implant (column 3, lines 54-66); at least partially transferring said generated data for a multi-dimensional prosthetic implant to a forming machine that is used to at least partially form said prosthetic implant (column 4, lines 7-15); at least partially forming said prosthetic implant by said forming machine (column 4, lines 41-55); and, generating history information pertaining to said prosthetic implant, said information including the materials used to form the prosthetic implant, the size and shape of information used to form the prosthetic implant, the internal features of said prosthetic implant, the type of additives included on and/or in said prosthetic implant, cavities included in the

Art Unit: 2123

prosthetic implant, surface features of the prosthetic implant, connectors included on the prosthetic implant, secondary structures included in the prosthetic implant, frame and/or support structures used to at least partially form the prosthetic implant, the day and/or time the prosthetic implant was manufactured, the patient's name, medical facility names, the physician names, the medical procedure used to insert the prosthetic implant, the location within the patient's body where the prosthetic implant is to be inserted, the date of implant of the prosthetic implant, the machine used to manufacture the prosthetic implant, the machine and/or name of the individual used to generate the data for the prosthetic implant, additives included in the prosthetic implant, modifications to the prosthetic implant, approval codes or signatures, and combinations thereof (column 3, lines 16-42, i.e., . The image data is then generally stored on disk or magnetic tape or other mass computer storage that can be provided to an image combiner).

Crook fails to specifically disclose spinal site including insertion is between two vertebrae. However, Fuss discloses spinal site including insertion is between two vertebrae (Abstract).

It would have been obvious to a person of ordinary skill in the art at the time of invention was made to modify the teachings of Crook with the teaching of Fuss in order to provide a support system extending over a plurality of vertebrae is provided externally of the spinal column near the implant for lending additional support, said system being attachable to the individual vertebrae.

Regarding claims 44 and 45, Crook discloses the step of obtaining information is at least partially obtained mechanically, chemically, electronically, and combinations thereof and the step of at least partially obtaining information electronically includes obtaining information by an ultrasonic device, a sound wave device, a magnetic wave device, an electromagnetic wave device, a heat detecting device, a camera, a scope, and combinations thereof (column 4, lines 56-64; column 5, lines 16-20).

Regarding claim 46, Crook discloses the prosthetic device is at least partially formed of a biocompatible material (column 4, lines 7-15) .

Regarding claim 47, Crook discloses the step of at least partially forming said prosthetic implant includes forming a material in said forming machine having a shape that is substantially similar to at least a portion of the multi-dimensional prosthetic implant generated by said at least one data processor (column 4, lines 41-55).

Regarding claim 53, Crook discloses prosthetic device includes at least one cavity, at least one outer wall opening, and combinations thereof (Fig. 6).

Regarding claim 54, Crook disclose the step of comparing said generated data for a multi-dimensional prosthetic implant to said obtained information about the site of implant, and further including the step of modifying said generated data when required (Fig. 11).

Regarding claim 55, Crook discloses forming machine including at least one mold cavity that can be varied in size, shape and combinations thereof (column 4, lines 7-15).

Regarding claim 56, Crook discloses the mold cavity is varied based at least partially on said generated data (column 4, lines 7-15).

Regarding claim 57, Crook discloses the said at least one data processor generates data that can be used to create at least one graphical representation of said prosthetic implant (Figs. 6-7).

Regarding claim 58, Crook discloses the including the step of manually modifying said generated data (Fig. 11).

Regarding claim 59, Crook discloses the said step of transferring at least a portion of the generated information to a molding machine includes a transmission device selected from the group consisting of wires, cables, electromagnetic waves, and combinations thereof (Fig. 3).

Regarding claim 60, Crook discloses the steps of flowing said at least one type of moldable compound into said forming machine, at least partially forming said prosthetic implant in said forming machine, and hardening at least a portion of said moldable compound (column 4, lines 16-55).

Regarding claim 66, Crook discloses the step of modifying at least a portion of said prosthetic implant after said prosthetic implant has been removed from said forming machine, said step of modifying including labeling, cutting, smoothing, minor sizing, disinfecting, etching, and combinations thereof (column 4, lines 16-55).

2. Claims 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crook (US Patent 5,365,996) in view of Dooley et al. (AUTOMATED DESIGN AND ANALYSIS SYSTEM FOR DESIGN OF CUSTOM ORTHOPEDIC IMPLANTS).

Regarding claim 67, Crook discloses obtaining information about the site of implant for the prosthetic implant and the bone that exists in the site of the implant or which exists in a site similar to the site of the implant, said step of at least partially obtaining information includes obtaining information by an ultrasonic device, a sound wave device, a magnetic wave device, an electromagnetic wave device, a heat detecting device, a camera, a scope, and combinations thereof (Fig. 3, column 4, lines 56-64; column 5, lines 16-20); manually entering said obtained information, electronically entering said obtained information, and combinations thereof about said site for processing by at least one data processor (Fig. 11); processing said manually entered information, said electronically entered information, and combinations thereof by said at least one data processor to generate data for a multi-dimensional prosthetic implant; d) at least partially transferring said generated data for a multi-dimensional prosthetic implant to a forming machine that is used to at least partially form said prosthetic implant; generating history information pertaining to said prosthetic implant, said information including the materials used to form the prosthetic implant, the size and shape information used to form the prosthetic implant, the internal features of said prosthetic implant, the type of additives included on and/or in said prosthetic implant, cavities included in the prosthetic implant, surface features of the prosthetic implant, connectors included on the prosthetic implant, secondary structures included in the prosthetic implant, frame and/or support structures used to at least partially form the prosthetic implant, the day and/or time the prosthetic implant was manufactured, the patient's name, medical facility names, the physician names, the medical procedure

used to insert the prosthetic implant, the location within the patient's body the prosthetic implant is to be inserted, the date of implant of the prosthetic implant, the machine used to manufacture the prosthetic implant, the machine and/or name of the individual used to generate the data for the prosthetic implant, additives included in the prosthetic implant; modifications to the prosthetic implant, approval codes or signatures, and combinations thereof (column 3, line 16-42).

Crock fails to disclose at least partially forming said prosthetic implant by said forming machine, said prosthetic implant selected from the group consisting of an implant that is a substitute for a complete bone or a portion of a bone, said prosthetic implant at least partially formed on or about at least one preexisting structure, said bone selected from the group consisting of acromion, atlas, axis, calcaneus, carpus, clavicle, coccyx, epicondyle, epitrochlea, femur, fibula, frontal bone, greater trochanter, humerus, ilium, ischium, mandible, maxilla, metacarpus, metatarsus, occipital bone, olecranon, parietal bone, patella, phalanx, radius, ribs, sacrum, scapula, sternum, talus, tarsus, temporal bone, tibia, ulna, or zygomatic bone, said step of at least partially forming said prosthetic implant includes forming a material in said forming machine having a shape that is substantially similar to at least a portion of the multi-dimensional prosthetic implant generated by said at least one data processor.

Dooley discloses at least partially forming said prosthetic implant by said forming machine, said prosthetic implant selected from the group consisting of an implant that is a substitute for a complete bone or a portion of a bone, said prosthetic implant at least

Art Unit: 2123

partially formed on or about at least one preexisting structure, said bone selected from the group consisting of acromion, atlas, axis, calcaneus, carpus, clavicle, coccyx, epicondyle, epitrochlea, femur, fibula, frontal bone, greater trochanter, humerus, ilium, ischium, mandible, maxilla, metacarpus, metatarsus, occipital bone, olecranon, parietal bone, patella, phalanx, radius, ribs, sacrum, scapula, sternum, talus, tarsus, temporal bone, tibia, ulna, or zygomatic bone, said step of at least partially forming said prosthetic implant includes forming a material in said forming machine having a shape that is substantially similar to at least a portion of the multi-dimensional prosthetic implant generated by said at least one data processor (page 406).

It would have been obvious to a person of ordinary skill in the art at the time of invention was made to modify the teaching of Crook with the teachings of Dooley in order to provide an improved method of making an implantable joint prosthesis which can provide improved prosthesis shafts not only from the point of view of the geometry of the bone passage, but also can ensure an extremely uniform distribution of the stresses.

3. Claims 48-52, 61-62, 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crook (US Patent 5,365,996) in view of Fuss et al. (US 6,562,072 and further view of Dooley et al. (AUTOMATED DESIGN AND ANALYSIS SYSTEM FOR DESIGN OF CUSTOM ORTHOPEDIC IMPLANTS)).

Crook and Fuss disclose that the limitations of claim 43 as stated in par. 1 but fail to disclose the limitations of claims 48-52, 61-62, 64-65. However, Dooley discloses that the limitations of 48-52, 61-62 and 64-65 as follows:

Regarding claims 48-52, Dooley discloses prosthetic device is formed at least partially bioabsorbable, partially moldable, one location marker, one biological additive, one biological additive (Fig.1).

Regarding claims 61-62, Dooley discloses the moldable compound is at least partially hardened by exposure to heat, radiation, catalysts, chemical reactants, electromagnetic waves, sound waves, and combinations thereof and the moldable compound includes a material selected from the group consisting of bone, cartilage, calcium-phosphate compounds, ceramics, metals, polymers, co-polymers, resins, thermoplastics, and mixtures thereof ((Page 406, i.e., implant constriction)

Regarding claims 64-65, Dooley discloses readable information on said prosthetic implant, said readable information including at least a portion of said history information said prosthetic implant is at least partially formed on or about at least one preexisting structure (Page 408, i.e., schemata).

It would have been obvious to a person of ordinary skill in the art at the time of invention was made to modify the teaching of Crook and Fuss with the teaching of Dooley in order to provide an improved method of making an implantable joint prosthesis which can provide improved prosthesis shafts not only from the point of view of the geometry of the bone passage, but also can ensure an extremely uniform distribution of the stresses.

Response to Arguments

4. Applicant's arguments with respect to claims 43-62 and 64-67 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kidest Bahta whose telephone number is 571-272-3737. If

Art Unit: 2123

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached on 571-272-3753. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval IPAIRI system. Status information for published applications may be obtained from either Private PMR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAG system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kidest Bahta/

Primary Examiner, Art Unit 2123